

LEH-35-98
U.S. Ser. No. 09/493,891

REMARKS

Following the entry of the amendments in the Response mailed November 18, 2005, Claims 1-3, 5-8, and 16-23 are pending in the application.

In the Final Office Action dated February 6, 2006, the Examiner made a number of rejections, some new, and some maintained. For clarity, the objections and rejections at issue are set forth by number in the order they are herein addressed:

1. Claims 1 and 16-22 are newly rejected under 35 USC 112, second paragraph, as being indefinite;
2. Claims 16-17 remain rejected under 35 USC 102(a) as anticipated by Martey et al. (CAPLUS abstract 1998: 529836, 1998);
3. Claims 1-3, 5, 6, 16, and 17, remain rejected under 35 USC 103(a) as obvious over Heindel (Bioconjugate Chem., 1994) in view of Diener (US Patent No. 4,415,552) and further in view of either Akanuma et al. (J. Biochem., 1978) or Martey et al. (CAPLUS abstract 1998: 529836, 1998);
4. Claims 3, 5, 16, 20, and 23 remain rejected under 35 USC 103(a) as obvious over Heindel (Bioconjugate Chem., 1994) in view of Weinshenker (US Patent No. 5,068,227) and further in view of either Akanuma et al. (J. Biochem., 1978) or Martey et al. (CAPLUS abstract 1998: 529836, 1998);
5. Claims 3, 5, 16, 21 and 23 remain rejected under 35 USC 103(a) as obvious over Heindel (Bioconjugate Chem., 1994) in view of Elson (US Patent No. 5,888,988) and further in view of either Akanuma et al. (J. Biochem., 1978) or Martey et al. (CAPLUS abstract 1998: 529836, 1998);
6. Claims 3, 5, 8, 16, 19, and 23 remain rejected under 35 USC 103(a) as obvious over Heindel (Bioconjugate Chem., 1994) in view of Hattori et al. (J. Agric. Food Chem., 1995) and further in view of either Akanuma et al. (J. Biochem., 1978) or Martey et al. (CAPLUS abstract 1998: 529836, 1998); and
7. Claims 3, 5, 7, 16, 18, 22, and 23 remain rejected under 35 USC 103(a) as obvious over Heindel (Bioconjugate Chem., 1994) in view of Mill (US Patent No.

Response to Office Action
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4,003,972) and further in view of Streitwieser et al. (Introduction to Organic Chemistry, 1976).

The previous rejections in the Office Action dated June 6, 2005 were not maintained, and are thus presumed overcome in the preceding Response to that Office Action.

1. Claims 1, 2, and 6-22 are rejected under 35 USC 112, second paragraph, as being indefinite; and
2. Claims 1 and 2 are rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement.

The Applicants believe that the claims as pending are allowable, for all of the reasons presented in the previous Response filed on November 18, 2005. However, in Response to the Final Office Action, the Applicants have filed a continuing patent application on April 21, 2006. The continuing patent application was filed for the purpose of furthering the Applicants' business goals and expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),¹ and without waiving the right to prosecute in the future the pending (or similar) claims of the present application in another application, and without acquiescing to any of the Examiner's arguments. A copy of the filing papers, along with the first page of the continuing patent application, are attached to this Response as **Exhibit 1**.

¹ 65 Fed. Reg. 54603 (September 8, 2000).

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CONCLUSION

If the Examiner has any questions or requires any additional information, the Examiner is invited and encouraged to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

By Jaen Andrews
Jaen Andrews
Registration No. 35,051
Attorney for Applicants

COMPETITIVE TECHNOLOGIES, INC.
1960 Bronson Road
Fairfield, CT 06824

Telephone: (203) 255-6044
Fax: (203) 254-1102

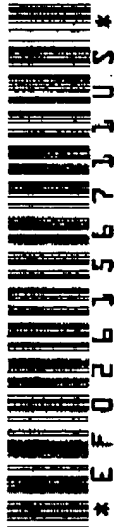
Response to Office Action
Page 5 of 6

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EXHIBIT 1

Response to Office Action
Page 6 of 6

Exhibit 1

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APR 28 2006

PTO/SB/05 (04-06)

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U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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UTILITY
PATENT APPLICATION
TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	LEH-35-98 CIP
First Inventor	Ned Heindel
Title	Lactones of Carboxylic Acid ...
Express Mail Label No.	EF026156711US

APPLICATION ELEMENTS

See MPEP chapter 800 concerning utility patent application contents.

1. ☒ Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original and a duplicate for fee processing)
2. ☒ Applicant claims email entity status.
See 37 CFR 1.27.
3. ☒ Specification [Total Pages 50]
Both the claims and abstract must start on a new page
(For information on the preferred arrangement, see MPEP 608.01(a))
4. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets 2]
5. Oath or Declaration [Total Sheets 3]
 - a. ☒ Newly executed (original or copy)
 - b. ☐ A copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Box 18 completed)
 - i. ☐ DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s)
name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☐ Application Data Sheet. See 37 CFR 1.76
7. ☐ CD-ROM or CD-R in duplicate, large table or
Computer Program (Appendix)
☐ Landscape Table on CD
8. Nucleotide and/or Amino Acid Sequence Submission
(if applicable, items a. - c. are required)
 - a. ☐ Computer Readable Form (CRF)
 - b. Specification Sequence Listing on:
 - i. ☐ CD-ROM or CD-R (2 copies); or
 - ii. ☐ Paper
 - c. ☐ Statements verifying identity of above copies

ADDRESS TO:

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers (cover sheet & document(s))
Name of Assignee _____
10. ☐ 37 CFR 3.73(b) Statement (when there is an assignee) ☐ Power of Attorney
11. ☐ English Translation Document (if applicable)
12. ☐ Information Disclosure Statement (PTO/SB/08 or PTO-1449)
☐ Copies of citations attached
13. ☐ Preliminary Amendment
14. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
15. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)
16. ☐ Nonpublication Request under 35 U.S.C. 122(b)(2)(B)(i).
Applicant must attach form PTO/SB/35 or equivalent.
17. ☐ Other: _____

18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:

☐ Continuation ☐ Divisional ☒ Continuation-in-part (CIP) of prior application No.: 09/493,891

Prior application information:

Examiner: Major, Leigh C.

Art Unit: 1823

19. CORRESPONDENCE ADDRESS

☒ The address associated with Customer Number:OR ☐ Correspondence address below

Name	PATENT TRADEMARK OFFICE			
Address				
City	State	Zip Code		
Country	Telephone	Email		
Signature	Date		4/21/2006	
Name (Print/Type)	Registration No.		35,051	
Jeen Andrews		(Attorney/Agent)		

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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APR 28 2006

PTO/SB/01 (10-05)

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**DECLARATION FOR UTILITY OR
DESIGN
PATENT APPLICATION
(37 CFR 1.63)**Declaration
Submitted
With Initial
Filing

OR

Declaration
Submitted after Initial
Filing (surcharge
(37 CFR 1.16 (e))
required)Attorney Docket
Number

LEH-35-98 CIP

First Named Inventor

Ned Helndel

COMPLETE IF KNOWN

Application Number

Filing Date

4/21/2006

Art Unit

Examiner Name

I hereby declare that:

Each inventor's residence, mailing address, and citizenship are as stated below next to their name.

I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Lactones of Carboxylic Acid Polysaccharides and Methods for Forming Conjugates Thereof

(Title of the Invention)

the specification of which



is attached hereto

OR



was filed on (MM/DD/YYYY)

as United States Application Number or PCT International

Application Number

and was amended on (MM/DD/YYYY)

(if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

(Page 1 of 2)

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.83. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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DECLARATION — Utility or Design Patent Application

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.					
NAME OF SOLE OR FIRST INVENTOR:			<input type="checkbox"/> A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))			Family Name or Surname		
Ned D.			Heindel		
Inventor's Signature					Date
Residence: City	State	Country	Citizenship		
Easton	PA	USA	US		
Mailing Address					
200 Hexenkopf Road					
City	State	Zip	Country		
Easton	PA	18042	USA		
<input checked="" type="checkbox"/> Additional inventors or a legal representative are being named on the 1 supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.					

(Page 2 of 2)

Ex 1-5

PTO/SB/02A (09-04)

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DECLARATION	ADDITIONAL INVENTOR(S) Supplemental Sheet
--------------------	---

Page 1 of 1

Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Wallace D.		Longton	
Inventor's Signature		Date	
Carlsle Residence: City	PA State	USA Country	US Citizenship
7 Derbyshire Drive			
Mailing Address			
Carlsle City	PA State	17013 Zip	USA Country
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Christine		Martoy	
Inventor's Signature		Date	
Somerset Residence: City	NJ State	USA Country	US Citizenship
132 Hempstead Drive			
Mailing Address			
Somerset City	NJ State	08873 Zip	USA Country
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Robert		Rapp	
Inventor's Signature		Date	
Laureldale Residence: City	PA State	USA Country	US Citizenship
1804 Elizabeth Avenue			
Mailing Address			
Laureldale City	PA State	18605 Zip	USA Country

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EX 1-6

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U.S. Patent Application
Docket No. 35-98 CIP**LACTONES OF CARBOXYLIC ACID POLYSACCHARIDES AND METHODS
FOR FORMING CONJUGATES THEREOF**

This application is a continuation-in-part of co-pending US Patent Application Serial No. 09/493,891, filed January 28, 2000, which is incorporated herein in its entirety, and claims the benefit of co-pending US Provisional Patent Application Serial No. 60/674,343, filed April 22, 2005, which is incorporated herein in its entirety.

FIELD OF THE INVENTION

The present invention relates to sustained release drug and other compound conjugates, and in particular to carboxymethylcellulose-drug conjugates, and to related carboxylic acid polysaccharide-bioactive compound conjugates.

BACKGROUND OF THE INVENTION

The treatment of many diseases often involves the administration of drugs. Such drugs may be biocides, as for example anti-bacterial or antiviral drugs, or they may supply missing metabolic intermediates or end-products, or they may inhibit or stimulate a normal metabolic pathway in the body. Not infrequently, such drugs have a limited or local target, and are toxic or have other untoward side effects when active outside the limited or local target. However, most drugs are delivered systemically, or non-specifically, as for example orally (by pills and liquids), by injection, and by transfusion, and reach approximately the same concentration throughout the body. On the other hand, it is difficult to reach certain targets with systemically delivered drugs; as an example, the blood-brain barrier prevents many circulating drugs from reaching the brain. Moreover, once administered, drugs are typically metabolized by the body to an inactive form, and/or excreted, thus exhibiting a short lifetime in the body and requiring frequent doses to maintain an effective concentration at the targeted site.

Therefore, it would be desirable to develop drug delivery systems that could deliver drugs directly to the desired target, or very nearby. This would result in therapeutically effective concentrations at the desired target, but with lower concentrations elsewhere in the

Ex 1-7

APR 28 2006

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Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL

For FY 2006

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT	(\$)	880
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Complete if Known

Application Number	
Filing Date	4/21/2006
First Named Inventor	Ned Heindel
Examiner Name	
Art Unit	
Attorney Docket No.	LEH-35-98 CIP

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 032634 Deposit Account Name: Competitive Technologies

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below

☐ Charge fee(s) indicated below, except for the filing fee

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17

☐ Credit any overpayments

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FEE CALCULATION (All the fees below are due upon filing or may be subject to a surcharge.)

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	\$500
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description

Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180
Total Claims	Extra Claims	Fee (\$)
16	0	
$\text{HP} - 20 \text{ or HP} = 0 \times =$		Fee Paid (\$)
HP = highest number of total claims paid for, if greater than 20.		Multiple Dependent Claims
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		Fee Paid (\$)
		180
		\$180

Indep. Claims	Extra Claims	Fee (\$)
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95	95	9500
96	96	9600
97	97	9700
98	98	9800
99	99	9900
100	100	10000

HP = highest number of independent claims paid for, if greater than 3

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

<u>Total Sheets</u>	<u>Extra Sheets</u>	<u>Number of each additional: 50 or fraction thereof</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>
50 - 100 =	0	150 = (round up to a whole number) x		

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Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge):

SUBMITTED BY

Signature	<i>Jaen Andrews</i>	Registration No. (Attorney/Agent) 35,051	Telephone 203-255-6044
Name (Print/Type)	Jaen Andrews	Date 4/21/2006	

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